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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,350	03/20/2001	Susan Lindquist	HO-P01979US2	1595
26271	7590	12/15/2004	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/812,350

Applicant(s)

LINDQUIST ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16,27-30,32-36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16,27-30,32-36 and 38-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The amendment and 1.132 Declaration of Susan L. Lindquist filed on 9/23/2004 have been entered.

Claims 1-16, 27-30, 32-36, and 38-44 are pending.

Claims 17-26, 31, and 37 have been canceled.

2. Claims 1-16, 27-30, 32-36, and 38-44 including SEQ ID NO:30 encoding SEQ ID NO:17 are examined in the present office action.

3. Rejections and objections not set forth below are withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### *Claim objection*

5. Claims 2, 4 are objected to for reading on non-elected inventions. Applicant's arguments filed 9/23/2004 have been fully considered but they are not persuasive.

Applicants contend that they are not required to cancel or amend a claim subject to species election (page 7, 5<sup>th</sup> paragraph).

The Office contends that nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another, as are different proteins structurally distinct chemical compounds and unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121

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and 37 CFR 1.141 *et seq* (see MPEP 803.04 and 2434). This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. Therefore, Applicant is requested to amend claims 2 and 4 to not include non-elected inventions.

### ***Written Description***

6. Claims 1, 3-16, 27-30, 32-36, and 38-44 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/24/2004. Applicant's arguments filed 9/23/2004 have been fully considered but they are not persuasive.

Applicants contend that they provide multiple specific plant Hsp100 family amino acid sequences and nucleic acid sequences in paragraphs 30 and 31 of the specification, respectively. Applicants assert that the pending claims are described clearly enough to notify those skilled in the art as to the metes and bounds of the invention. Applicants contend that the proteins are structurally related to Arabidopsis Hsp101, and for example, Applicants provide description of nucleotide binding domains flanked by N-terminal, spacer, and C-terminal regions. Applicants contend that structural features should not be required to be recited in the claims, given that Applicants have provided a representative number of polynucleotides encoding plant Hsp100 family members in a sufficiently restricted genus scope (page 9 of the response, 2<sup>nd</sup> and 3<sup>rd</sup> full

paragraphs). Applicants contend that the specification provides sufficient written description for the aspects of the invention identified by the office (page 10, top paragraph).

The Office contends that Applicants have satisfied the written description requirement for claims drawn to SEQ ID NO:30 encoding SEQ ID NO:17, and plant transformation therewith. But, the Office contends that Applicants have not satisfied the written description requirement for claims drawn to nucleic acid sequences encoding a plant Hsp100 family amino acid sequence wherein said nucleic acid sequence encodes an amino acid sequence that has at least about 60%, 70%, or 80% overall amino acid identity to SEQ ID NO:17 and protects a plant or cell against heat. The Office acknowledges Applicants' disclosure of nucleic acid sequences encoding amino acid sequences in paragraphs 30 and 31, but Applicants have not disclosed which of the disclosed nucleic acid sequences falls within the scope of Applicants' claimed invention. The Office appreciates Applicants' submission of the alignment between SEQ ID NO:17 and the HSP17.7 and HSP21 proteins. To satisfy the written description requirement for claims drawn to nucleic acid sequences encoding an amino acid sequence that has at least about 60%, 70%, or 80% identity to SEQ ID NO:17, Applicants can submit an alignment of those sequences disclosed in paragraphs 30, 31, 59, 60 or 61 that exhibit at least about 60%, 70%, or 80% identity to SEQ ID NO:17 and wherein said protein when expressed in a plant or plant cell protects the plant or plant cell against heat. In addition, Applicants have not disclosed essential regions of the claimed genus of polypeptides that when expressed in a plant or plant cell protects the plant or plant cell from heat, wherein said regions are required by the claimed protein for functionality, i.e., protects the plant against heat. Disclosing regions that are conserved among all members of the Hsp100 or Arabidopsis Hsp101 proteins, including those proteins that do not protect a plant

or plant cell against heat, when transformed into a plant, does not satisfy the written description requirement. It is further noted that many heat shock proteins have functions other than the Hsp100 family, as stated in the Lindquist declaration of 9/23/2004. It is unclear whether Applicants have demonstrated sequence domains which are not shared by other heat shock proteins, and which are unique to the Hsp100 family, as required by *Lilly*.

### ***Scope of Enablement***

7. Claims 1, 3-16, 27-30, 32-36, and 38-44 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transgenic plants, methods of increasing stress tolerance of a plant, and method of producing a crop comprising overexpressing a nucleic acid encoding the Arabidopsis Hsp101 of SEQ ID NO:17, does not reasonably provide enablement for claims broadly drawn to transgenic plants, methods of increasing stress tolerance of a plant, and method of producing a crop comprising overexpressing any nucleic acid sequence encoding any plant Hsp100 family amino acid sequence wherein said nucleic acid sequence encodes an amino acid sequence that has at least about 60%, 70%, or 80% overall amino acid identity to SEQ ID NO:17, wherein the nucleic acid sequence is operably linked to a constitutive or heat inducible promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 3/24/2004. Applicant's arguments filed 9/23/2004 have been fully considered but they are not persuasive.

Applicants contend that it is well known in the art how to obtain the desired sequences from the NCBI's GenBank database, and how to isolate any of the sequences based on the direction provided; and methods of how to make or isolate them are well known techniques (page 11, 3<sup>rd</sup> paragraph). In addition, Applicants contend that it would not be undue experimentation to identify a sequence having the proper similarity to SEQ ID NO:30, for example, obtain it by polymerase chain reaction, clone it into an appropriate vector, transform the plant and test for thermotolerance (page 11, bottom paragraph). Applicants contend that every operable species is not required (page 12, top paragraph).

The Office contends that the techniques and methods of isolating sequences are known in the art. But, what is not known in the art, and what has not been disclosed by Applicants, is nucleic acid sequences or amino acid sequences that can be used to identify and then subsequently isolate, heat shock proteins that are 60%, 70% or 80% identical to SEQ ID NO:17 that when overexpressed in a plant or plant cell protect the plant or plant cell against heat. Applicants have only disclosed one sequence, i.e, SEQ ID NO:30 encoding SEQ ID NO:17. Undue trial and error experimentation would be required by one skilled in the art to screen through all the possible sequences using undisclosed sequences of SEQ ID NO:30, or the corresponding nucleic acid sequences encoding undisclosed regions of SEQ ID NO:17 as probes or primers, and isolating the fragments and subcloning the fragments into vectors to be transformed into plants. Undue experimentation would have also been required to screen through all the plants for those, if any, that are protected against heat, given the evidence of unpredictability regarding the phenotype conferred by transgenes encoding heat shock proteins, as demonstrated by the publication cited on pages 10-11 of the last office action.

Regarding inoperative embodiments, see *Atlas Powder v. DuPont*, 224 USPQ 409, 414 (Fed. Cir. 1984), where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation. Given the claim breadth and unpredictability as discussed above and in the last Office action, it appears that the majority of the embodiments encompassed by the claims would be inoperative, and thus prohibited by *Atlas*.

Applicants contend that they have disclosed a number of species of plant Hsp100 family members in paragraphs 30, 31, 59, 60 and 61 of the specification and directions for their requirements (page 12, 3<sup>rd</sup> paragraph).

The office contends that Applicants have merely disclosed a list of nucleic acid and amino acid sequences. Applicants have not disclosed, for example, by way of alignment, those sequences that fall within the scope of applicants' claims; i.e., encode a protein exhibiting at least about 60%, 70% or 80% identity with SEQ ID NO:17 and wherein when transformed into a plant protect said plant against heat. Furthermore, the Hsp100 family appears to be only a small subset of heat shock proteins, as taught by the Lindquist declaration of 9/23/2004, and no guidance has been provided regarding the particular conserved sequences which may be used to selectively recover genes encoding this family.

Applicants contend that they have compared sequences disclosed within paragraph 60 to SEQ ID NO:17 and have identified those that exhibit at least about 60% overall amino acid identity to SEQ ID NO:17. Said sequences are SEQ ID NO:18-24 and 27-28.

Applicants are invited to submit a 1.132 declaration disclosing the sequence identity of SEQ ID NO:18-24 and 27-28 compared to SEQ ID NO:17, accompanied with a demonstration that said sequence when over-expressed in a plant, protect said plant against heat.



8. No claims are allowed.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
December 8, 2004

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP ~~180~~ 1638

*David 76*